



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

NuVasive, Incorporated
Ms. Olga Lewis
Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

November 20, 2014

Re: K141896
Trade/Device Name: NuVasive® CoRoent® System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 22, 2014
Received: October 23, 2014

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141896

Device Name

NuVasive® CoRoent® System

Indications for Use (Describe)

The NuVasive CoRoent System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The implants are designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation system cleared by the FDA for use in the lumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The CoRoent System (L and XL platforms) are intended for use at either one level or two contiguous levels in the lumbar spine, from L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the CoRoent System (L and XL platforms) can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Olga Lewis
Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: November 18, 2014

B. Device Name

Trade or Proprietary Name:	<i>NuVasive[®] CoRoent[®] System</i>
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device

Device Class:	Class II
Classification:	21 CFR § 888.3080
Product Code:	MAX

C. Predicate Devices

The subject *NuVasive CoRoent System* is substantially equivalent to the primary predicate device, *Medtronic CAPSTONE Spinal System* (K123027), and additional predicate devices, *NuVasive CoRoent System* (K071795), *NuVasive CoRoent Titanium System* (K120918), *NuVasive CoRoent Sterile Implants System* (K132601), and *NuVasive CoRoent Thoracolumbar Implants* (K140659).

D. Device Description

The *CoRoent System* implants are manufactured from PEEK-Optima[®] LT-1 conforming to ASTM F2026 or titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The PEEK device contains titanium alloy radiographic markers conforming to ASTM F136/ ASTM F1472 or tantalum markers conforming to ASTM 560/ ISO 13782. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. This 510(k) is to modify the indications for use to include treatment of degenerative scoliosis.

E. Intended Use

The *NuVasive CoRoent System* is indicated for intervertebral body fusion of the spine in skeletally mature patients. The implants are designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation system cleared by the FDA for use in the lumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.



The *CoRoent System* (L and XL platforms) are intended for use at either one level or two contiguous levels in the lumbar spine, from L1-L2 to L5-S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the *CoRoent System* (L and XL platforms) can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive CoRoent System* are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. There have been no design changes to the implants previously cleared in the predicate 510(k)s. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

To establish substantial equivalence with predicate devices for the modified indications for use, published retrospective clinical data for the *CoRoent System* as well as devices similar to the subject spinal system were provided in support of this application.

The results demonstrate that the subject *NuVasive System* is substantially equivalent to the predicate devices.

H. Conclusions

Based on the technological characteristics, comparison to predicate devices, and clinical performance data, the subject *NuVasive CoRoent System* has been shown to be substantially equivalent to legally marketed predicate devices.